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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,158	12/05/2001	Janc Brandman	A0000483-01-CA	4222

7590 11/26/2004

RAYMOND R. MANDRA, ESQ.
FITZPATRICK, CELLA, HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112-3801

EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,158	BRANDMAN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 12, 2004 has been entered.

Claims 9 and 10 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Redmond (Contraception, 1998;58:29S-33S) and Thorneycroft et al. (Contraception, 1999;60:255-262) in view of Boissonneault (US Patent 5,010,070), references of record in the previous office action mailed October 1, 2002.

Redmond teaches an oral contraceptive, triphasic combination of norgestimate and ethinyl estradiol (TriCyclen® with gradually increased norgestimate dosage of 0.18, 0.215, 0.25 μg and fixed ethinyl estradiol daosage of 35μg), is effective in treating acne vulgaris (See particularly the abstract).

Thorneycroft et al. teaches two oral contraceptives, Alesse® (containing 100μg of levonorgestrel and 20μg of ethinyl estradiol) and Loestrin® Fe 1/20 (containing 1mg of norethindrone acetate and 20μg of ethinyl estradiol), are effective in reducing acne (See particularly the abstract, also page 257, col. 2 – page 259, col. 2; also Figure 2 and Tables 3 and 4). Thorneycroft et al. also teaches that several other studies have shown oral contraceptive regimens as effective in treating acne and improving acne condition (See page 260, col. 2, first full paragraph to page 261col. 1, line 3).

The references do not expressly teach the specific herein claimed dosage regimen of Estrostep or an effective amount of 1mg norethindrone acetate and a gradually increasing dose of ethinyl estradiol: 20μg for 5days, 30μg for 7 days and 35μg for 9 days.

Boissonneault teaches the specific herein claimed regimen of norethindrone acetate and ethinyl estradiol is useful as oral contraceptive having the advantages of

reducing the side effects associated with oral contraceptives (See col. 2, lines 23-43, col. 3, Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed regimen of administering norethindroe and ethinyl estradiol to treat acne vulgaris.

One of ordinary skill in the art would have been motivated to employ the herein claimed regimen of administering norethindrone acetate and ethinyl estradiol to treat acne vulgaris. Firstly, based on the cited prior art, it is known that different oral contraceptives containing different progestins and ethinyl estradiol are useful in treating acne vulgaris. Therefore, using yet another known oral contraceptives, such as Estrostep (taught by Boissonneault), in the treatment of acne vulgaris would be reasonably expect to be effective. Secondly, Boissonneault's regimens can reduce the unwanted side effects of oral contraceptives. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would be motivated to employ the herein claimed regimen, which is taught by Boissonneault, in the method of treating acne, absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed August 12, 2004 averring the cited prior arts' failure to teach oral contraceptive as effective in treating acne have been fully considered but they are not persuasive. It is clear from the teachings of the cited prior arts that the oral contraceptive treatments in both Redmond and Thorneycroft et al. that the total acne

lesion have been decreased after the oral contraceptive treatment. Such observation in Redmond and Thorneycroft et al. can also be seen in other studies using oral contraceptives as the acne treatment (See Thorneycroft et al., page 260, col. 2, first full paragraph to page 261col. 1, line 3). Therefore, it is clear that oral contraceptives is useful in treating acne, absent evidence to the contrary. No such evidence is seen to be present herein.

Applicant's arguments filed August 12, 2004 averring the ineffectiveness of Thorneycroft's regimen in treating acne because the number of inflammatory lesions is not significantly decreased have been considered, but are not found persuasive. It is clear that the regimens taught in Thorneycroft's study and other studies confirm the fact that oral contraceptive as effective in improving and treating acne. Applicant's arguments are directed to inflammatory lesions, which is an unclaimed limitation. Arguments directed to unclaimed limitations are considered moot.

Applicant's arguments filed August 12, 2004 directed to Schoonen have been considered, but are moot since Schoonen is no longer cited as a references in the rejections under 35 USC 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617